

**FDA STAFF MANUAL GUIDES, VOLUME I - ORGANIZATIONS AND  
FUNCTIONS**

**FOOD AND DRUG ADMINISTRATION**

**OFFICE OF MEDICAL PRODUCTS AND TOBACCO**

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**OFFICE OF TRANSLATIONAL SCIENCES**

**OFFICE OF COMPUTATIONAL SCIENCE**

Effective Date: 12/10/2012

**1. OFFICE OF COMPUTATIONAL SCIENCE (DKKNGD).**

The Office of Computational Science (OCS) is being established to address the need for leadership and management of the modernization of CDER's scientific computing abilities and operations. The OCS will be responsible for providing oversight of the development of CDER's scientific computing capabilities, including both infrastructure and operations. This will require that the organization ensures alignment with other Center and Agency initiatives, e.g., JANUS Clinical Data Repository, and coordinates with the various governance bodies that exist, e.g., the Agency Bioinformatics.

- A. Promotes efficient and informative data analysis methods to support the quantitative analysis of the efficacy, safety, and dosing of drugs through collaboration with various offices in CDER and Centers in FDA.
- B. Provides leadership, direction, policy development, and coordination to CDER on strategic scientific computing plans and plans for implementation.
- C. Develops communication plans to ensure timely information sharing and listening to both internal and external stakeholders.
- D. Plans for the development and adoption of data and data exchange standards to support CDER's regulatory and research missions, in coordination with the FDA Data Standards Council (DSC).
- E. Ensures the effective implementation and operations including:
  - The availability of an up-to-date hardware and software infrastructure

and systems support that enable needed data access and data analysis.

- The availability of statistical/technical competencies and services to facilitate data access, analysis and study conduct.
- F. Provides leadership, advocacy, direction, scientific skill, coordination, and tracking for all projects associated with the improvement of CDER regulatory informatics supports.
- G. Catalyzes an interdisciplinary approach to organizational change through collaboration with other disciplines in CDER to enhance integration of scientific computing in regulatory review.

## **2. AUTHORITY AND EFFECTIVE DATE.**

The functional statements for this Division were approved by the Director, Center for Drug Evaluation and Research on December 10, 2012.

**FOOD AND DRUG ADMINISTRATION  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
CENTER FOR DRUG EVALUATIONS AND RESEARCH  
OFFICE OF COMPUTATIONAL SCIENCE**

**OFFICE OF THE DIRECTOR**

---

STAFF MANUAL GUIDE 1268.5  
ORGANIZATIONS AND FUNCTIONS  
EFFECTIVE DATE: 12/10/2012

The following is the Food and Drug Administration, Office of Medical Products and Tobacco, Center for Drug Evaluation and Research, Office of Translational Sciences, Office of Computational Science organization structure depicting all the organizational structures reporting to the Office Director.

OFFICE OF COMPUTATIONAL SCIENCE